algroup lonza
fine chemicals and specialties

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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852
USA

01 October 1999/Our ref: corresp/fda/cooplet09-99

Draft guidance for industry
Cooperative manufacturing arrangements for licensed biologics
(Docket number: 990092013)

Dear Dr Yetter

Lonza Biologics are pleased to have the opportunity to comment on the above draft Guidance for Industry.

Lonza Biologics find the guidance document extremely useful as it provides clear guidance and alleviates many of our concerns regarding shared manufacturing arrangements versus contract manufacturing arrangements. Lonza Biologics believe that its mode of operation fits well within the description of a shared manufacturing arrangement and intends to actively encourage clients to enter into this type of arrangement. Many clients are willing to enter into this type of arrangement, however, some are expressing concern with regard to the labelling requirements, where the name(s), address(es) and licence number(s) of preceding intermediate product manufacturers participating in the shared manufacturing arrangement must be included in the description section of the product package insert.

Lonza Biologics would be grateful if CBER could review the requirement to identify the shared manufacturer in the package insert. Your views are welcomed such that Lonza Biologics are in a position to discuss this with our clients.

Yours sincerely
lonza biologics plc

Lynne Hill M R Pharm S
Director of Quality and Regulatory Services
Authorised Official

99D-2013

C7

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1 From

Date 1 Oct 99

Phone 01753 777000

Sender's Name BARBARA JOYCE

Company LONZA BIOLOGICS PLC

Address 228 BATH ROAD

Dept/Floor

Address SLOUGH

City UK

State/Province

ZIP/Postal Code SL1 4DY

Country

PowerShip

2 Your Internal Billing Reference Information 7962

3 To

Phone

Recipient's Name DR YETTER

Company DOCKETS MANAGEMENT BRANCH (HFM-305)

Address FOOD AND DRUG ADMINISTRATION

Dept/Floor

Address 5360 FISHERS LANE, ROOM 1061

City ROCKVILLE

State/Province

ZIP/Postal Code MD 20852

Country USA

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DOCUMENTS		UK	NCV

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☐ [redacted] 29 ☐

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